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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,226	02/26/2007	Karina-Ethel Petit	U25.12-0001	1347

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EXAMINER

GALLIS, DAVID E

ART UNIT	PAPER NUMBER
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1625

MAIL DATE	DELIVERY MODE
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05/15/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/581,226	Applicant(s) PETIT ET AL.	
	Examiner DAVID E. GALLIS	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 14-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 14-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/10/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1 through 5 and 14 through 37 are pending. Claims 1 through 5 have been amended. Claims 6 through 13 have been canceled. Claims 14 through 37 have been newly added. Applicants' claim to foreign priority by application FRANCE 0314167 filed December 2, 2003 is acknowledged.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1 through 5 and 14 through 37 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a *Rhytisma fulvum* fraction with neuroactivity in a cockroach, does not reasonably provide enablement for neuroactivity in general by a compound of formula (0) or more specifically by 6S-acetyl-4R,5R-dimethyl-1R(10S)-epoxy-2R-hydroxy-7R-acetoxyl-decahydronaphthalene. Furthermore, the specification does not reasonably provide enablement for the chemical synthesis of a compound of formula (0) or more specifically 6S-acetyl-4R,5R-dimethyl-1R(10S)-epoxy-2R-hydroxy-7R-acetoxyl-decahydronaphthalene. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. While the isolation of a *Rhytisma fulvum* fraction with neuroactivity in a cockroach is described in the instant specification, there is no information relating to the assignment of the formula (0) or 6S-acetyl-4R,5R-dimethyl-1R(10S)-epoxy-2R-hydroxy-

7R-acetoxyldecahydronaphthalene structure and conformation. This information can not be deduced from chromatographic R_f and retention time values. Additionally, the instant specification offers no direction regarding the chemical synthesis of a compound of formula (0) or more specifically 6S-acetyl-4R,5R-dimethyl-1R(10S)-epoxy-2R-hydroxy-7R-acetoxyldecahydronaphthalene. Natural products, due to their conformational dependence, are well known for being extremely difficult to chemically synthesize and would not be synthetically obvious to one of skill in the art.

“The factors to be considered in making an enablement rejection have been summarized as a) the quantity of experimentation necessary, b) the amount of direction or guidance presented, c) the presence or absence of working examples, d) the nature of the invention, e) the state of the prior art, f) the relative skill of those in that art, g) the predictability or unpredictability of the art, h) and the breadth of the claims”, *In re Rainer*, 146 USPQ 218 (1965); *In re Colianni*, 195 USPQ 150, *Ex parte Formal*, 230 USPQ 546.

a) Characterization of the active component(s) of the *Rhytisma fulvum* fraction would require extensive experimentation. b) The direction concerning fraction isolation is found in the disclosure on pages 9 through 11, but offers no characterization of the active component. c) There is no disclosed working example of the synthesis of a compound of formula (0), or more specifically, 6S-acetyl-4R,5R-dimethyl-1R(10S)-epoxy-2R-hydroxy-7R-acetoxyldecahydronaphthalene. e) The state of the art currently lacks any method of structure assignment using chromatographic properties. f) Artisans using Applicants' invention would require a Ph.D. in synthetic and analytical chemistries, and also several years of experience with natural products. g) It is well established that

"the scope of enablement varies inversely with the degree of unpredictability of the factors involved", and components of natural fractions, as well as synthetic pathways for their synthesis, are generally considered to be an unpredictable factor. h) The breadth of the claims includes properties assigned to compounds of a speculative nature and not assigned to known structures.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David E. Gallis whose telephone number is 571-272-9068. The examiner can normally be reached on Mon-Thur 8:30-7:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-1600. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information

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system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Janet L. Andres/

Supervisory Patent Examiner, Art Unit 1625

David E. Gallis

Patent Examiner